510(K) SUMMARY

Date: February 25, 2002

OCT 0 8 2002

Company:
Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Contact:
Dawn E. Frazer
Vice President
Regulatory Affairs & Quality Assurance
(978) 670-2422 x243
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Subject Device: Model 4310 PSArray² EEG Electrode

Classification: Class II, CFR 21 Part 882.1320, Cutaneous Electrodes

Intended Use: The Physiometrix PSArray² EEG Electrode is applied directly to the patient's skin to enable recording of electrophysiologic signals (such as EEG).

Description: The Physiometrix Model 4310, PSArray² EEG Electrode, is a single-use, disposable, pre-gelled electrode array. The PSArray² is comprised of six (6) electrodes located at F7, Fp1, FpZ', FpZ, Fp2 and F8. The electrode is packaged with 1 electrode per pouch, 25 pouches per box and 4 boxes per case.

The electrodes are mounted in a polyethylene foam coated with a pressure sensitive adhesive. The electrode pad is an area of silver/silver chloride ink that is connected to cable connector by a silver ink trace. An electrolyte gel is held in place over the electrode pad by a open-cell polyurethane sponge located in wells created by the foam basepad. The electrolyte gel was selected for its low impedance properties. No pre-application prepping is required to achieve adequate impedance levels for operation of the PSA4000.

The PSArray² EEG Electrode is connected to the PSA4000 System via a patient cable that attaches to the substrate connector. The PSArray² is designed for use with the PSA4000 System.

Predicate Device: K001055, Model 4300, PSArray EEG Electrode

Similarities: The PSArray² is similar to the predicate device in the following ways:
a. The intended use is same.
b. The technology is same.
c. The materials are the same.

Differences: The PSArra²y is different from the predicate device in the following way:
a. The PSArray² has 6 electrodes while the predicate device has 7 electrodes.

Test Results: Electrical testing was conducted in accordance with the American National Standard for Disposable ECG Electrodes, AAMI/ANSI EC-12 (1991). The PSArray² device exceeded requirements indicated in the standard.

Biocompatibility testing was conducted in accordance with the International Standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing and FDA Guidance, "Protocol for Dermal Toxicity Testing for Medical Devices In Contact with Skin." The skin contact materials were determined to be safe for contact with skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PHYSIOMETRIX INC.
Dawn E. Frazer
Vice President, Regulatory Affairs & Quality Assurance
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North Billerica,Massachusetts 01862

APR - 9 2012

Re: K020670
Trade/Device Name: PSArray² EEG Electrode Model 4310
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated (Date on orig SE ltr): October 7, 2002
Received (Date on orig SE ltr): October 7, 2002

Dear Ms. Frazer:

This letter corrects our substantially equivalent letter of October 8, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant:	Physiometrix, Inc.
510(k) Number (if known)	Not assigned
Device Name	Model 4310 PSArray^2 EEG Electrode
Indications For Use	The Physiometrix PSArray^2 EEG Electrode is applied directly to the patient's skin to enable recording of electrophysiologic (such as EEG) signals.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020670